

AZD0466 clinical DEP® program global expansion

- AZD0466 clinical development program expanded to incorporate global clinical trial
- Clinical expansion facilitates patient recruitment into a global Phase 1 study in haematological tumours
- AZD0466 is a highly optimised nanomedicine formulation of AstraZeneca's novel dual Bcl2/xL inhibitor which utilises Starpharma's DEP® technology

Melbourne, Australia; 9 February 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that it had been advised by AstraZeneca of its intention to expand the clinical program for AZD0466 to include a multi-centre global Phase 1 study. The study will recruit patients with acute leukaemias.

AZD0466 is a highly optimised nanomedicine formulation of AstraZeneca's novel dual Bcl2/xL inhibitor which utilises Starpharma's DEP® technology. Preclinical data presented at the 2020 AACR¹ Annual Meeting has shown significant improvement in therapeutic index delivered by the DEP® technology, which enabled the progression of AZD0466 into the clinic. [Three scientific posters](#) highlighted the potent and broad ranging anti-cancer activity of AZD0466 which results from the dual Bcl2 and Bcl/xL activity and provided positive preclinical data for AZD0466 in haematological cancers, including those resistant to venetoclax (Venclexta™ - AbbVie/Genentech). AZD0466 demonstrated superior anti-cancer activity in preclinical models of haematological cancers, including Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL) and Non-Hodgkin's Lymphoma.

Dr Jackie Fairley, CEO of Starpharma commented: "We are excited to see the global expansion of the clinical program for AZD0466 and AstraZeneca's commitment to bringing this important medicine to patients in need, as quickly as possible. There has been great enthusiasm for the global study from investigators and we understand that the intention is to expedite development of AZD0466 with the objective of obtaining regulatory approval for specific indications of high unmet clinical need. We look forward to further progress and clinical data for this exciting oncology medicine".

Bcl inhibitors have attracted a lot of interest due to their role in cancer cell death (apoptosis), and the unique dual Bcl2/xL inhibition by AZD0466 holds significant promise for both haematological and solid cancers. Bcl2 is a clinically validated oncology target with the Bcl2 inhibitor, venetoclax, being approved by the US FDA in 2016.

About AZD0466

AZD0466 is a dendrimer-based formulation of a novel dual Bcl2/xL inhibitor developed under Starpharma's multi-product DEP® licence with AstraZeneca. AZD0466 utilises DEP® to improve the formulation characteristics and therapeutic index of the anti-cancer agent and is currently in a phase 1 trial in the US. AZD0466 is described as having the potential to be a 'best-in-class' agent with a broad opportunity in solid and haematological tumours (blood cancers) due to its ability to target both Bcl2 and Bcl/xL. AZD0466 has demonstrated excellent anti-cancer activity in a wide range of preclinical tumour models including Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), Non-Hodgkin's Lymphoma and Small Cell Lung Cancer (SCLC).

The development of AZD0466 is being progressed under a multi-product licence whereby Starpharma is eligible to receive development, launch and sales milestones.

¹ American Association for Cancer Research (AACR)

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for COVID-19, DEP[®] drug delivery and VivaGel[®]. Starpharma is developing VIRALEZE[™], an antiviral nasal spray for COVID-19 which is complementary to vaccines and other preventative measures such as distancing and PPE. VIRALEZE[™] also has potential use in future pandemics and is afforded expedited development because it is repurposing an already-marketed, broad-spectrum antiviral dendrimer, SPL7013. SPL7013 is utilised in approved products - the VivaGel[®] condom and VivaGel[®] BV. VivaGel[®] BV has been licensed in >160 countries, is approved in >40 countries and available in for sale in the UK, Europe, South East Asia, Australia and New Zealand.

As a leading company in dendrimer based drug delivery, Starpharma's proprietary drug delivery platform technology, DEP[®], which is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP[®] versions of existing drugs, particularly in the area of anti-cancer therapies. DEP[®] partnerships include programs with AstraZeneca and other world leading pharmaceutical companies, which have the potential to generate significant future milestones and royalties.

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Media: Summit Media

Grant Titmus
Mob: +61 419 388 161
grant@sumitmedia.com.au

Starpharma Holdings Limited

Dr Jackie Fairley, Chief Executive Officer
Nigel Baade, CFO and Company Secretary
+61 3 8532 2704
investor.relations@starpharma.com
4-6 Southampton Crescent
Abbotsford Vic 3067

Disclosure

This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.

Forward Looking Statements

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.